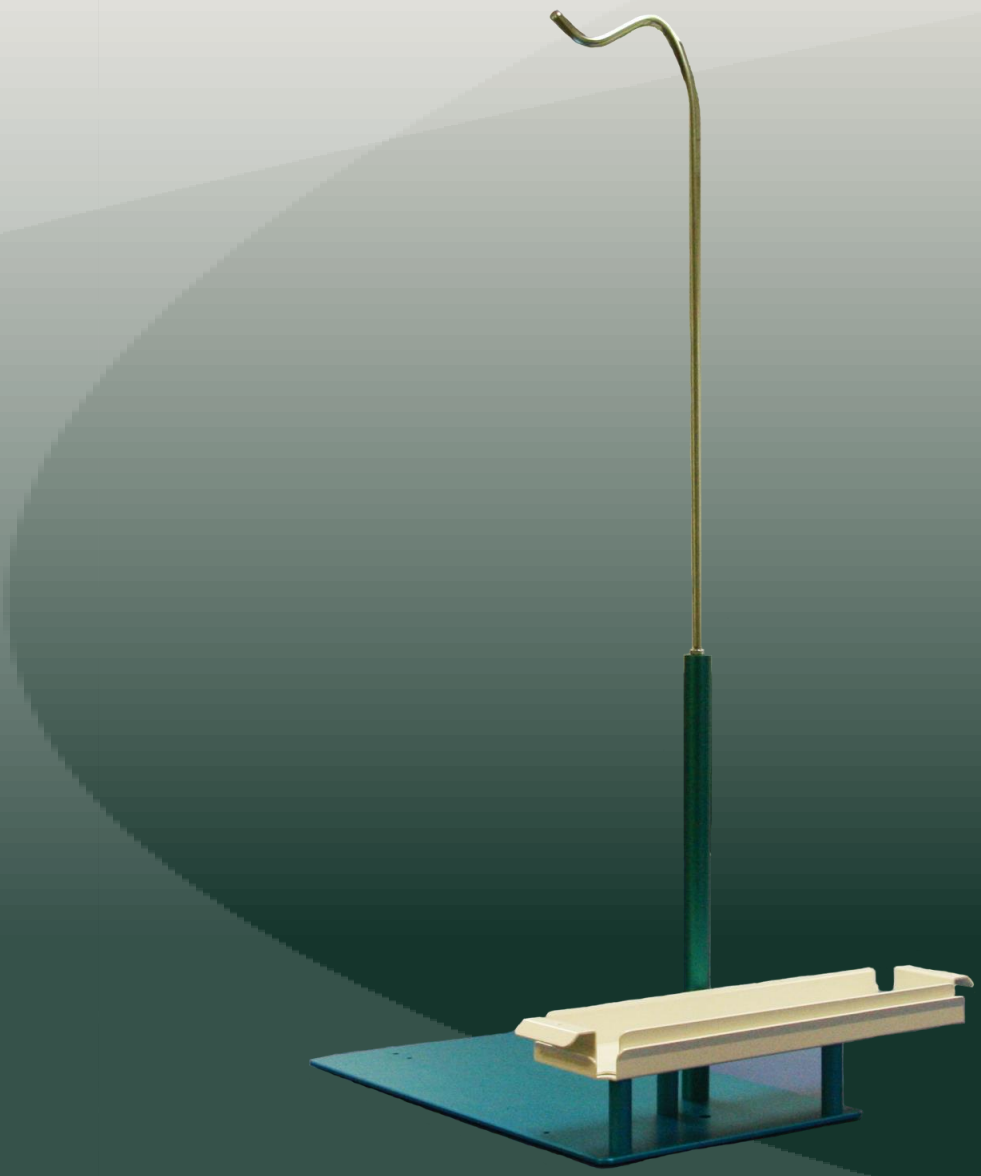
SynGen™



Sterile Docking Workstation

USER MANUAL

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It is strongly recommended that all users read this information for use document in its entirety before using the SynGen™ Sterile Docking Workstation.

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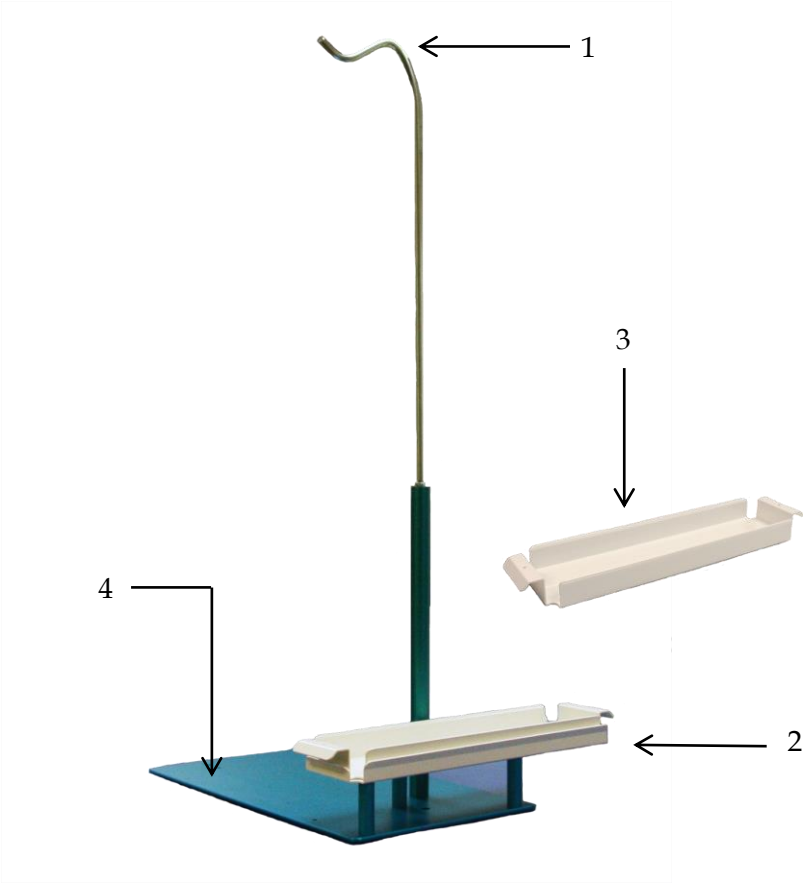
Introduction

The Sterile Docking Workstation (SDW) provides an easy and convenient means of sterile docking up to four cord blood collection bags to the input tubing of up to four SynGenX™-1000 Disposable Cartridges (DC) and the buffy coat transfer tubing of the Disposable Cartridges to up to four CryoPRO-2 Cryopreservation/Storage Bag Sets. It also facilitates the transfer of the cord blood from the collection bag into the disposable cartridge by gravity.



SynGen Sterile Docking Workstation

1. The **Collection Bag Hanger** is used to hang the blood bag received from the collection center to be transferred to the DC.
2. The **Tray** is used to seat the DC/CM holder in place.
3. The **DC/CM Holder** is used to hold a maximum of four Disposable Cartridges or Disposable Cartridges with Control Modules for easy and convenient transfer to the centrifuge.
4. The **Base** has sufficient area to hold a Tube Welder.

Symbol Key

The following symbols and abbreviations are used on the Sterile Docking Workstation labeling, packaging, or within the User Manual.

REF	Product or Part Number
	Manufacturer
SN	Serial Number
	Warning to be observed by the user
	Precaution to be observed by the user
	A note to be observed by the user
	Consult Instructions For Use
DC	Disposable Cartridge
CM	Control Module
SDW	Sterile Docking Workstation

Warning

A warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device

READ THIS USER MANUAL COMPLETELY PRIOR TO USING THE SYNGEN™ STERILE DOCKING WORKSTATION

- Always follow internal policy for personal protective equipment such as gloves, gowns, eyewear, or masks when using the SynGen Sterile Docking Workstation.
- Always follow established procedures for handling bio hazardous materials.

Precautions

A precaution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.

- Follow aseptic procedures
- Users should be trained on the Sterile Docking Workstation prior to initial use
- Handle the Sterile Docking Workstation with care
- Avoid dropping the Sterile Docking Workstation as it may cause damage or injury

Specifications

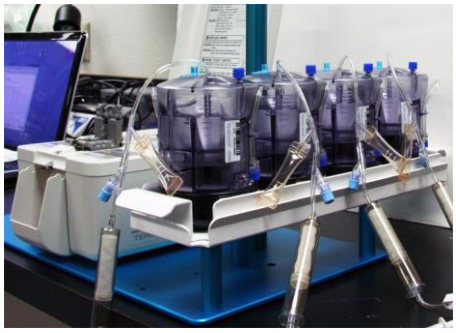
Feature	Specification
Height	38.25 inches (97.16 cm)
Width	19.75 inches (50.67 cm)
Depth	18.75 inches (47.63 cm)
Weight	8.40 lbs. (3.81 kg)
Operating Environment	
Operates under standard laboratory environment conditions.	

Operating Instructions

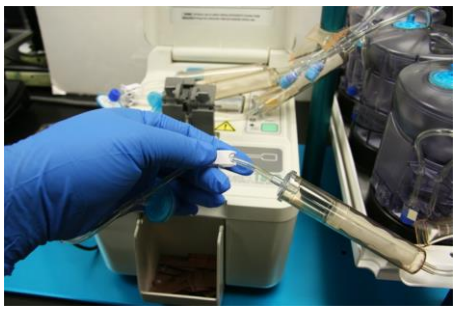
It is strongly recommended that users review the entire manual and operating instructions prior to initial system use.

The instructions below are performed using a Terumo Sterile Tubing Welder (TSCD II), for sterile docking SynGen Disposable Cartridges and CryoPRO-2 Bag Sets

Transfer of Cord Blood From Blood Bag Collection To Disposable Cartridge



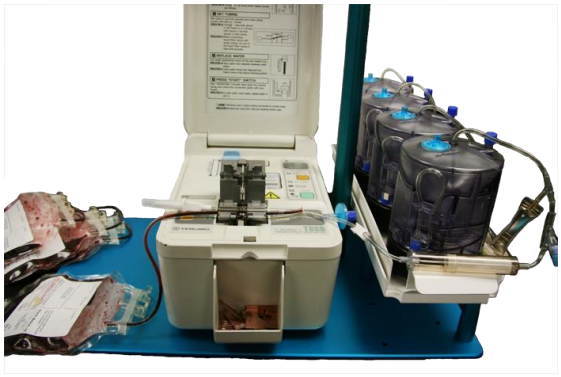
1.) Place four DCs with control modules onto the SDW DC/CM Holder.



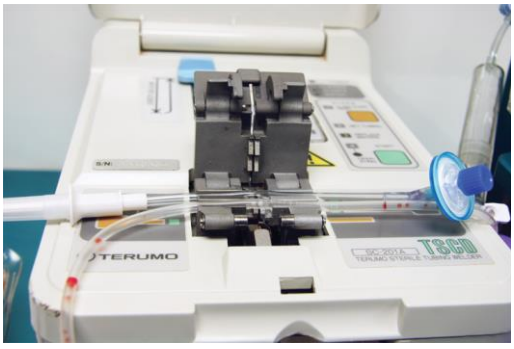
2.) Close the clamp on the DCs input tubing for all four DCs.

3.) Repeat the following steps for all four DCs.

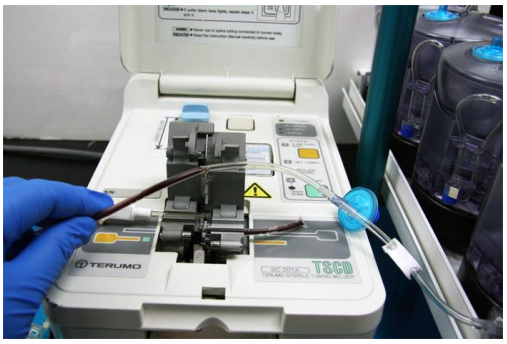
4.) Place the input tubing of the DCs into the rear groove of the Tubing Welder clamp. Position the tube so that the welding point is half way between the spike and the HES filter.



5.) Place the Blood Collection Bag to the left side of the Tubing Welder, similar to the image above.

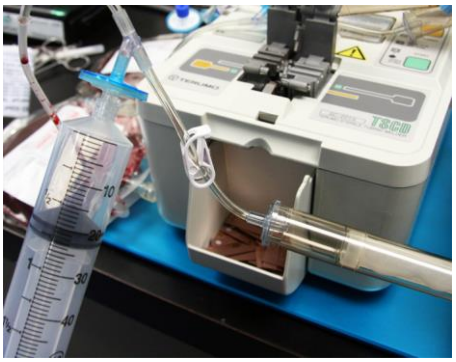


6.) Place the collection bag tube into the front groove of the Tubing Welder clamp.



7.) Close the Tubing Welder clamp. Operate the Tubing Welder to create the weld as per the manufacture's instructions. Open the Tubing Welder clamp. Inspect the welding point. If the weld is complete, gently massage the weld until the tubing is open. Attach

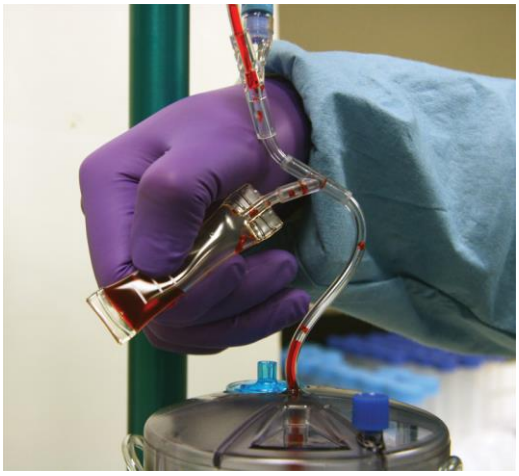
the Blood Unit ID label to the DC and verify that it is same as on the Blood Collection Bag.



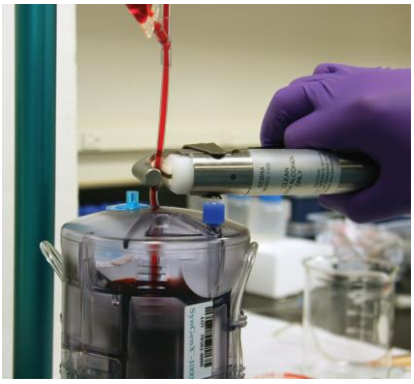
8.) Keeping the collection bag on the surface of the sterile docking workstation, attach a syringe filled with approximately 20 ml of air to the HES filter. Inject the air into the collection bag and recap the HES filter.

9.) Mix the collection bag thoroughly by inverting the bag 10 times.

10.) Hang the blood bag on the Blood Bag Hanger above the DC. Open the pinch clamp on the disposable cartridge input tubing. Allow the blood to flow into the disposable cartridge for ~10 seconds.



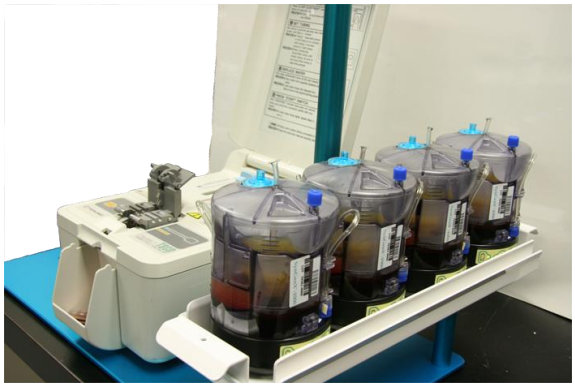
11.) Take a pre-sample by pressing then releasing the sample bulb on the input tubing. Each line on the sample tube is 0.5 ml. Allow the blood to finish flowing into the DC. Manipulate the bag to get as much blood into the DC as possible. Attach the Blood Unit ID label (same as on DC and Blood Collection bag) to the sampling bulb.



12.) Seal the DC input tubing ~1 inch above the top of the cartridge.

13.) After all four DCs are filled, remove the collection bags for processing of the pre-sample. Lift the DC/CM Holder to transport for centrifugation.

Sterile Connection of DC to the CryoPRO-2 Bag Set **(Repeat the steps for each DC in the DC/CM Holder)**



1.) After centrifugation place all four DC/CMs onto the DC/CM Holder. Place the sample access tubing of the BC chamber of the DC into the rear groove of the Tubing Welder clamp. Position the tube so that there is little to no slack in the tubing.

2.) Place the input tubing of the CryoPRO-2 Bag set into the front groove of the sterile docking station clamp. Position the tube so that there is little to no slack in the tubing. Close the sterile docking station clamp. Operate the sterile docking station to create the weld as per the manufacture's instructions. Open the sterile docking station clamp. Inspect the welding point. If the weld is complete gently massage the weld until the tubing is open.

3.) Attach the same Blood Unit ID label as on the DC to the Freezing Bag of the CryoPRO-2 Bag set.

4.) Repeat Step 3 for all other DCs.

5.) After all four DCs are attached to the four CryoPRO-2 Bag sets, lift the tray to transport the DC/CryoPRO-2 Bag sets pair for addition and mixing of cryoprotectant. (see SynGenX-1000 User Manual).

Maintenance and Disinfection

Internal policy for personal protective equipment such as gloves, gowns, eyewear, or masks should be followed when disinfecting SynGen equipment.

Use a dry cloth or paper towel to wipe away any liquid that maybe present. Then, wet a paper towel with a 10% bleach solution or a 70% isopropyl alcohol solution and wipe down all outside surfaces. Allow the solution to stay on the surface for 5 minutes then dry with a paper towel. Besides disinfection, there is no other routine maintenance required.

Customer Service & Technical Assistance

For assistance with technical or application issues, please contact your account representative or SynGen Customer Service at (844) 363-0709 (USA) or (916) 256-2423 (International).

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Warranty

SynGen warrants to original purchaser that the SynGen Sterile Docking Workstation will be free from defects in material or workmanship for one (1) year from date of shipment.

SynGen also warrants that spare parts will be free from defects in material workmanship for a period of ninety days (90), or maximum time required by applicable local law, from date of shipment of spare part.

SynGen products are designed and manufactured to provide trouble free and reliable performance when properly maintained and used in accordance with the instructions provided in this manual.

In case of device failure or malfunction, SynGen will replace or repair the Sterile Docking Workstation according to the agreement in place.

Device failure or malfunction for reasons other than those caused by defects in materials or manufacturing defect (such as improper handling of the device, misuse, accident, or non-compliance with the User Manual) is not covered under the SynGen warranty program and such device will be replaced or repaired at the charge of the end-user.

Any alterations or modification made to the device (other than those made by SynGen) will render the warranty null and void. SynGen will not be responsible for any consequential or incidental damages resulting from device malfunction or loss of use of device.

SynGen shall under no circumstances be liable for consequential or economic damage that may be an indirect or direct consequence of a defective part.